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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,553	01/27/2004	Deepankar Chatterjee	Q74006	9897

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EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/764,553	<b>Applicant(s)</b> CHATTERJEE, DEEPANKAR	
	<b>Examiner</b> David Guzo	<b>Art Unit</b> 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-29 is/are pending in the application.
- 4a) Of the above claim(s) 13-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **Detailed Action**

Claims 13-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/13/06.

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

This requirement is reiterated.

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Applicant, in the response filed 9/5/06, indicates that it is believed that the specification is sufficient and it is not clear what changes should be made.

Applicant's arguments filed 9/5/06 have been fully considered but they are not persuasive. The examiner is somewhat confused by applicant's response, as the specification is replete with numerous grammatical errors and confusing sentences which need to be corrected. For example, on Page 1, applicant recites:

In *Streptomyces coelicolor*, ppGpp has been implicated in synthesis of antibiotics in the stationary phase of the bacteria (Chakraborty and Bibb, 1997) Though ppGpp has been detected in various other prokaryotes e.g. *Bacillus subtilis* (Ochi et al. 1982), *Bacillus stearothermophilus* (Fehr and Richter, 1981), *Staphylococci* (Cassel et al. 1995), *Streptococcus equisimilis* (Mechold et al. 1996), *Salmonella typhimurium* (Kramer et al. 1988; Shand et al. 1989) under starvation, its function in these organisms is yet to be assigned.

It is unclear if this run-on sentence is one or two sentences since the word "Though" in line 2 is capitalized but there is no period after "(Chakraborty and Bibb, 1997)"

On page 2 of the specification, applicant recites:

Such common metabolic pathways leading to the survival of the organism have been known since sometime now. Extensive work to prove that latent *M.tb* can indeed be represented by *M.smegmatis* under depleted carbon source has been carried out and well known (Ojha et al., 2002). The studies by Ojha et al (2002) describe some of the recent observations to validate this model and establish that without these recent observations the present invention and model cannot be supported.

The first sentence here is confusing in that it is unclear what "the organism" referred to in line 1 is. Also, the phrase "known since sometime now" appears to be a verbatim translation from some foreign language. The phrase "latent *M.tb* can indeed be represented by *M.smegmatis*" is confusing because it is unclear what "represented by" means.

On Page 2 of the specification, applicant recites:

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It has also been characterised the in vivo function of *M.tuberculosis* relA/spoT homologue in *M.smegmatis* (Ojha et al, 2000).

This sentence is not in proper idiomatic English.

These are a few of the problems on **just the first two pages** of the specification! Also, throughout the specification, articles which should precede nouns are missing.

The requirement for a substitute specification is maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have presented, in the amendment filed 9/5/06, new claim 23 which recites a Mycobacterium promoter, wherein the promoter is stable in *M. smegmatis* and *E. coli*, and consists essentially of the 200 base pair fragment upstream and adjacent to the *Mycobacterium tuberculosis* relA/SpoT gene. Applicants use the transitional phrase "consisting essentially of" to attempt to refer to the "essential property" of the promoter and differentiate it from the promoter sequence disclosed by Fleischmann et al. (applied as a 102(b) reference in the previous Office Action).

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The specification, as filed, does not provide explicit or implicit support for use of the transitional phrase "consisting essentially of". As noted by applicant and the MPEP, the transitional phrase "consisting essentially of" occupies a middle ground between closed claims using "consisting of" language and fully open claims using "comprising" language. Also, as noted in MPEP section 2163:

"By using the term consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A consisting essentially of claim occupies a middle ground between closed claims that are written in a consisting of format and fully open claims that are drafted in a comprising' format." *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998).

and

If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ256 (CCPA 1964).

and

The claim as a whole, including all limitations found in the preamble (see *Pac-Tec Inc. v. Amerace Corp.*, 903 F.2d 796, 801, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990) (determining that preamble language that constitutes a structural limitation is actually part of the claimed invention)), **the transitional phrase** (emphasis added), and the body of the claim, must be sufficiently supported to satisfy the written description requirement. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

In the instant case, applicant claims a 200 bp portion of the promoter of the *relA*/SpoT gene. Neither applicant's specification nor arguments provide evidence of additional components (sequences) which do, or do not, affect the characteristics of applicant's

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invention. Since the instant 200 bp sequence is a portion of a larger promoter, it is unclear what additional *relA*/*SpoT* promoter sequences (or other *M. tuberculosis* sequences) would materially change the characteristics of the claimed invention (See also MPEP 2105).

Also, there is no support in the specification as filed for a *Mycobacterium* promoter which **consists essentially of the 200 base pair fragment upstream and adjacent to the *Mycobacterium tuberculosis relA/SpoT* gene.** The specification provides support for a 200 bp (SEQ ID NO:2) fragment of the promoter of the *relA/SpoT* gene. Claim 23, as presented, reads on a *M. tuberculosis* promoter fragment which is upstream and adjacent to the *relA/SpoT* gene. The word "adjacent" does not necessarily mean that the 200 bp fragment is next to the *relA/SpoT* gene as "adjacent" can mean next to or close to the other element. The specification does not use the term "adjacent" to describe the relationship between the 200 bp fragment and the *relA/SpoT* gene and hence this term broadens the nature of the invention to an extent not supported by the specification. Finally, claim 23 recites **any** 200 bp promoter fragment upstream and adjacent to the *M. tuberculosis relA/SpoT* gene, while the instant specification provides support only for the 200 bp sequence of SEQ ID NO:2. This is a NEW MATTER rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Fleischmann et al.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Applicant argues that Fleischmann et al. does not teach a *M. tuberculosis* promoter that consists essentially of the 200bp fragment upstream and adjacent to the *relA/SpoT* gene.

Applicant's arguments filed 9/5/06 have been fully considered but they are not persuasive. Initially, it is again noted that neither applicant's specification nor arguments provide evidence of additional components (sequences) which do, or do not, affect the characteristics of applicant's invention. Since the instant 200 bp sequence is a portion of a larger promoter, it is unclear what additional *relA/SpoT* promoter sequences (or other *M. tuberculosis* sequences) would materially change the characteristics of the claimed invention. As noted in MPEP 2163:

For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1239-1240, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003); *In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963).



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Therefore, since "consisting essentially of" in the current context will be construed as "comprising", the art as exemplified by Fleischmann et al. still applies, as it teaches a *Mycobacterium tuberculosis* relA/SpoT promoter sequence which comprises a 200 base pair fragment upstream and adjacent to the relA/SpoT gene. The stability of the promoter fragment in *E. coli* and *M. smegmatis* appears to be an inherent feature of the relA/SpoT promoter. Claim 27 is included because it appears to recite an inherent characteristic of the relA/SpoT promoter recited in claim 23.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 (and dependent claims) are vague in that there is no antecedent basis for the phrase "the 200 base pair fragment".

Claim 27 is vague in that it is unclear what heat shock promoter applicant is referring to. The claim appears to read on any heat shock promoter followed by a specific heat shock promoter in parentheses ( $P_{hsp60}$ ). The metes and bounds of the claimed invention are therefore unclear.

Any rejections not reiterated in this Office Action are withdrawn.

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No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
November 17, 2006

  
DAVID GUZO  
PRIMARY EXAMINER